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EXAMINER	
WHITEMAN, BRIAN A	
ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 12/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/069,386	ALAOUI-JAMALI ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) 8 and 9 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-7 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 2/19/02 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 10/28/02.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Non-Final Rejection

Claims 1-9 are pending.

The amendment to the claims filed on 2/19/02 is acknowledged.

The examiner has considered the international search report and the international examination report

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-6, drawn to a gene encoding a protein essentially consisting in the amino acid sequence as set forth in SEQ ID NO: 2; a protein consisting of the amino acid sequence set forth in SEQ ID NO: 2; and method of gene therapy comprising using the gene as a promoter for over expressing a gene in a suitable tissue.

Group II, claim(s) 8, drawn to an antibody raised against a gene encoding a protein essentially consisting in the amino acid sequence as set forth in SEQ ID NO: 2.

Group III, claim(s) 9, drawn to an antisense hybridizing to a mRNA encoding the protein set forth in SEQ ID NO: 2.

The inventions listed as Groups I-III do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

37 CFR 1.475(b) states:

"An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

37 CFR 1.475(c) states:

"If an application contains claims to more or less than one of the combination of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

37 CFR 1.475(d) also states:

"If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c)."

37 CFR 1.475(e) further states:

"The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternative within a single claim."

In view of 37 CFR 1.475 (b), 37 CFR 1.475 (c), 37 CFR 1.475 (d), and 37 CFR 1.475 (e), Group I is considered the main invention to the product first mentioned in the claims, and the first recited invention drawn to other categories related thereto, e.g. a method of making, method of use.

The special technical feature of Group I is considered to be a gene encoding a protein essentially consisting in the amino acid sequence as set forth in SEQ ID NO: 2.

The special technical feature of Group II is considered to be an antibody.

The special technical feature of Group III is considered to be to an antisense oligonucleotide hybridizing to a mRNA encoding a protein as set forth in SEQ ID NO: 2.

Accordingly, Groups I-III are not so linked by the same or a corresponding technical feature as to form a single general inventive concept.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

During a telephone conversation with Joseph Zucchero on 9/20/04 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-6. Affirmation of this election must be made by applicant in replying to this Office action. Claims 7 and 8 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Specification

The abstract of the disclosure is objected to because: The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text. Correction is required. See MPEP § 608.01(b).

Claim Objections

Claims 2, 4, and 6 are objected to because of the following informalities: the phrase "a gene according to claim" in claims 2 and 6 and the phrase "a protein according to claim 3" are grammatically incorrect phrases for dependent claims.

Suggest amending the phrases to read:

-- The gene according to claim 1 -- in claims 2 and 6; and

-- the protein according to claim 3 -- in claim 4.

Appropriate correction is required.

Claim 6 is objected to because of the following informalities: the claim is missing a period at the end of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 101

Claim 7 was not examined under 101 for the reasons set forth under 112 second paragraph.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-4, as written, do not sufficiently distinguish over nucleic acids or proteins, as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor. See MPEP 2105.

Claim Rejections - 35 USC § 112

Claim 7 was not examined under 112 first paragraph written description and enablement for the reasons set forth under 112 second paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 5, and 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The following rejections are new matter rejections.

The limitation 'A gene encoding a protein essentially consisting in the amino acid sequence as set forth in SEQ ID NO: 2' in amended claim 1 filed on 2/19/02 is not supported by the as-filed specification. Applicant has not pointed out where the amended claim is supported, nor does there appear to be a written description of the claim limitation 'A gene encoding a protein essentially consisting in the amino acid sequence as set forth in SEQ ID NO: 2' in the application as filed. See MPEP § 2163.06.

Claims 2, 5, and 6 are rejected under 112 first paragraph written description because the claims are dependent on claim 1.

The limitation 'use of a gene according to claim 1 as a promoter for overexpressing a gene in a suitable tissue' in claims 5 and 6 is not supported by the as-filed specification. Applicant has not pointed out where the claim is supported, nor does there appear to be a written description of the claim limitation 'use of a gene according to claim as a promoter for overexpressing a gene in a suitable tissue' in the application as filed. See MPEP § 2163.06. The specification discloses that amino acid sequence (SEQ ID NO: 2) encoded by SEQ ID NO: 1 acts as a transcriptional activator and not as a promoter.

Claims 1, 2, 4, 5, and 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The following rejection is for inadequate written description.

The specification contemplates a genus of genes having characteristics of a gene encoded by a nucleotide sequence as set forth in Fig.1, SEQ ID NO: 1 (page 4). The specification further contemplates that the gene may be from a human, a mouse, a rat or a yeast (page 4). The specification contemplates that the amino acid sequence set forth in SEQ ID NO: 2 may be from a human, a mouse, a rat, or yeast. The specification provides sufficient description of a nucleotide sequence comprising SEQ ID NO: 1 or a nucleotide sequence encoding SEQ ID NO: 2. SEQ ID NO: 2 is a protein interactor of RPA32 subunit of Replication Protein A (RPA). The specification does not disclose how the nucleotide sequence was made or from where the nucleotide sequence was isolated.

The term "gene" in the claims read on a gene found in a genomic sequence. The specification does not disclose how to make a gene comprising SEQ ID NO: 1 or a gene encoding SEQ ID NO: 2. The specification does not disclose what organism has a gene comprising SEQ ID NO: 1 or a gene encoding SEQ ID NO: 2. The specification demonstrates that BLAST homology searches against the deduced amino acid sequence of RBT1 reveal that it is an undefined protein with little homology to known protein sequences. The specification also demonstrates that BLASTN homology searches only identified approximately 20 human expressed sequences tags (ESTs), which has high homology to RBT1. However, the specification does not disclose what gene(s) are associated with any of the human ESTs with high homology to SEQ ID NO: 2. The specification does not disclose a known correlation

between the structure and function of the nucleotide sequence encoding the amino acid sequence as set forth in SEQ ID NO: 2 to the genus of claimed genes. The prior art teaches that there is no structure and function correlation between an EST and a gene because of the high level of redundancy found among transcribed sequences and common experimental artifacts (Gerhold et al. BioEssays, 18:973-981, 1996). The prior art also teaches that an EST might come from a unique gene or from a member of a gene family in which all the genes have the same or very similar sequences (Gerhold, supra).

Furthermore, the art of record teaches that there is a variation between a gene selected from a human, a mouse, a rat, or yeast. For example, if the amino acid sequence set forth in SEQ ID NO: 2 was encoded by a gene from a human, SEQ ID NO: 2 would not be 100% identical to the protein encoded by a similar gene found in a mouse, a rat or yeast. The specification does not disclose a number of species of known genes in the art to sufficiently describe the genus of genes having the characteristics of a gene encoding a protein essentially consisting in the amino acid sequence as set forth in SEQ ID NO: 2. It is not apparent that on the basis of the applicant's disclosure an adequate written description of the invention defined by the claims requires more than a mere statement that it is part of the claimed invention and reference to potential methods and/or classes of molecules that are essential for the genus of genes that must exhibit the disclosed biological functions as contemplated by the specification.

The statement that, "a gene having the characteristics of a gene encoded by a nucleotide sequence as set forth in Fig.1 (SEQ ID NO: 1)", is not sufficient to support the present claimed invention directed to a genus of claimed genes. The claimed invention as a whole is not adequately described if the claims require essential or critical elements, which are not adequately

described in the specification and which is not conventional in the art as of applicant's effective filing date. Claiming a genus of genes, that must possess the biological properties as contemplated by applicant's disclosure without defining what means will do so is not in compliance with the written description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CAFC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998). The skilled artisan cannot envision the detailed structure of a genus of genes that must exhibit the contemplated biological functions, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the structures and/or methods disclosed in the as-filed specification. Thus, in view of the reasons set forth above, one skilled in the art at the time the invention was made would not have recognized that applicant was in possession of the claimed invention as presently claimed.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 5 was not examined under 112 first paragraph enablement for the reasons set forth under 112 second paragraph.

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in In re Wands, 858 F.2d 731, 8USPQ2d 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art without undue experimentation (United States v. Telectronics, Inc., 8 USPQ2d 1217 (Fed. Cir. 1988). Whether undue experimentation is required is not based upon a single factor, but rather a conclusion reached by many factors. These factors were outlined in Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in In Re Wands (see above).

Applicants claim using a gene encoding a protein essentially consisting in the amino acid sequence set forth in SEQ ID NO: 2 as a promoter for overexpressing a gene in a suitable tissue. The scope of the claimed invention is very broad, encompassing a large number of genes that may or may not be used in the claimed invention.

Applicants teach a replicational protein A binding transcriptional activator 1 (RBT1) (SEQ ID NO: 2) of the RPA32 subunit of Replication Protein A (RPA). RBT1 interacts with the RPA32 subunit of Replication Protein A (RPA). Applicants further teach that RBT1 acts a strong transcriptional activator in yeast and mammalian cells (e.g., cancer cells).

With respect to claim 6 directed to using a gene encoding SEQ ID NO: 2 as a promoter for overexpressing a gene in a suitable tissue, the claim is not considered enabled because the specification and the prior art are absent for using a transcriptional activator as a promoter for overexpressing a gene in a tissue. Applicants provide no working example of the claimed

invention. The specification contemplates using SEQ ID NO: 2 as a transcriptional activator to promote expression of RPA. However, the relevance of this data to the *in vivo* methods is unclear at best because neither the applicants nor the prior art provide a correlation or nexus between the results obtained in *in vitro* studies such as those provided by applicants with results which the skilled artisan would reasonably expect to see *in vivo*. The specification does not teach the skilled artisan how promoting expression of RPA can be used in a method of gene therapy. Thus, to the extent the claim fails to recite distinguishing features to commensurate with the level of guidance presented, the claim is not considered enabled.

Furthermore, with respect to using a gene according to claim 1 as a promoter for overexpressing a gene in a suitable tissue, the claim embraces a genus of genes that is not supported by the specification or the prior art. As stated above, the specification discloses using RBT1 to promote the expression of RPA32 in a cell. Applicants do not teach the skilled artisan what genes other then a gene encoding RPA32 can be overexpressed using RBT1. The prior art does not provide sufficient guidance on the subject to overcome the deficiencies of the instant specification. There is no guidance in the prior art that allows the skilled artisan to use a representative number of genes in the claimed method.

Given the analysis of the factors which the courts have determine are critical in determining whether a claimed invention is enabled, it must be concluded that the skilled artisan would have needed to conduct undue and unpredictable trial and error experimentation to practice the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "gene" in claim 1 is a relative term, which renders the claim indefinite. The term "gene" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds of the term are not defined because the definition of the term is unclear in the art. See Attwood, Science, Vol. 290: 471-473, 2000.

Claims 2 and 5-6 are also rejected because they depend on claim 1.

Claims 2 and 4 are rejected under 112 second paragraph because the claims are indefinite. The claims read on a gene or a protein from a mouse, a rat, a human and a yeast having the same amino acid sequence as set forth in SEQ ID NO: 2. The art of record indicates that there is a variation between a gene and a protein from different species or organisms. Thus, a rat, human, mouse, and yeast cannot have the same amino acid sequence set forth in SEQ ID NO: 2.

Claim 6 is rejected under 112 second paragraph because the term "using a gene according to claim 1 as a promoter for over-expressing a gene in a suitable tissue" is indefinite. The

specification discloses that the amino acid comprising SEQ ID NO: 2 acts as a transcriptional activator and not as a promoter.

The term "essentially consisting" in claims 1 and 3 is a relative term, which renders the claims indefinite. The term "essentially consisting" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds of the term are not defined because it is not clear if the protein is the amino acid sequence as set forth in SEQ ID NO: 2 or is within the amino acid sequence set forth in SEQ ID NO: 2 or is similar in some way to SEQ ID NO: 2. If the latter, it is unclear how similar it must be to read on the claims.

Claims 2 and 4-6 are rejected under 112 second paragraph because the claims are dependent on either claim 1 or claim 3.

Claim 5 provides for the use of gene according to claim 1 for the preparation of a medicament for gene therapy, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 5 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex*

parte Dunki, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The claim could not be examined under 112 first paragraph enablement because it is too unclear what the applicants are claiming.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: method steps to complete the pre-amble of the claim.

Claim 7 is rejected under 112, second paragraph, because the metes and bounds of claim 7 are indefinite because the claim depends on itself.

The claim could be examined no further because it is too unclear what the applicants are claiming.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, SPE - Art Unit 1635, can be reached at (571) 272-0760.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal

Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Scott D. Priebe

SCOTT D. PRIEBE, PH.D
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